

Melissa E. Flax, Esq.
Michael Cross, Esq.
CARELLA BYRNE CECCHI
OLSTEIN BRODY & AGNELLO, PC
5 Becker Farm Road
Roseland, NJ 07068
(973) 994-1700
mflax@carellabyrne.com
mcross@carellabyrne.com

*Attorneys for Defendant
Sagent Pharmaceuticals, Inc.*

Stephen R. Auten, Esq.
Brian P. Murray, Esq.
TAFT STETTINIUS & HOLLISTER
LLP
111 East Wacker Dr., Suite 2800
Chicago, IL 60601
312-527-4000
sauten@taftlaw.com
bmurray@taftlaw.com

*Attorneys for Defendant
Sagent Pharmaceuticals, Inc.*

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

HELSINN HEALTHCARE S.A,

Plaintiff,

v.

SAGENT PHARMACEUTICALS, INC.,

Defendant.

CA. No. 2-16-cv-00173 SRC-CLW

**DECLARATION OF ROSHAN P. SHRESTHA, PH.D., ESQ.
IN SUPPORT OF SAGENT'S MOTION**

I, Roshan P. Shrestha, Ph.D., hereby certify pursuant to 28 U.S.C. § 1746 that:

1. I am an attorney at law in the State of Illinois and am associated with the law firm of Taft Stettinius & Hollister LLP, attorney for Defendant Sagent Pharma., Inc. ("Sagent") in the above captioned matter.

2. Attached as Exhibit 1 is a true and correct copy of the FDA webpage showing Sagent's ANDA No. 204289 received tentative approval from the FDA on August 7, 2017.
3. Attached as Exhibit 2 is a true and correct copy of the FDA webpage showing Sagent's ANDA No. 205870 received tentative approval from the FDA on April 20, 2018.
4. Attached as Exhibit 3 is a true and correct copy of July 25, 2016 Settlement and License Agreement between Helsinn and Sagent. (Filed under seal).
5. Attached as Exhibit 4 is a true and correct copy of August 2, 2016 Dismissal Order of Action No. 16-173.
6. Attached as Exhibit 5 is a true and correct copy of August 2, 2016 Dismissal Order of Action No. 16-681.
7. Attached as Exhibit 6 is a true and correct copy of the March 26, 2018 Cipla Press Release regarding the launch of its authorized generic ALOXI®.
8. Attached as Exhibit 7 is a true and correct copy of the March 26, 2018 Dr. Reddy's Press Release regarding the launch of its generic ALOXI®.
9. Attached as Exhibit 8 is a true and correct copy of page 48 of FDA's list of first applicants showing generic ALOXI® (palonosetron hydrochloride) ANDA application(s) were filed on May 27, 2011.
10. Attached as Exhibit 9 is a true and correct copy of the March 23, 2018 Teva Press Release regarding the launch of its generic ALOXI®.
11. Attached as Exhibit 10 is a true and correct copy of the January 30, 2018 Denial of Helsinn's Request for Injunction in Civ. A. No. 14-4274, D.I. 89.
12. Attached as Exhibit 11 is a true and correct copy of the December 30, 2014 Dismissal Order of Sandoz in Civ. A. No. 11-3962, D.I. 247.
13. Attached as Exhibit 12 is a true and correct copy of the January 12, 2015 Helsinn Press Release regarding its settlement with Sandoz in the ALOXI® case.
14. Attached as Exhibit 13 is a true and correct copy of a news article by Salazar, D., titled "Sandoz Launches Its Aloxi Generic," in Drug Store News, dated April 2, 2018 regarding Sandoz's launch of its generic ALOXI®.
15. Attached as Exhibit 14 is a true and correct copy of Sandoz's final FDA Approval Letter.
16. Attached as Exhibit 15 is a true and correct copy of the October 16, 2015 Stipulation of Dismissal of Dr. Reddy's in Civ. A. No. 11-3962, D.I. 355.
17. Attached as Exhibit 16 is a true and correct copy of the October 13, 2015 Helsinn Press Release regarding its settlement with Dr. Reddy's in the ALOXI® case.

18. Attached as Exhibit 17 is a true and correct copy of Dr. Reddy's Final Approval Letter.
19. Attached as Exhibit 18 is a true and correct copy of March 28, 2018 letter from S. Auten to M. Missaglia and J. O'Malley (Filed under seal).
20. Attached as Exhibit 19 is a true and correct copy of April 4, 2018 letter from M. Missaglia to S. Auten *et al.* (Filed under seal).
21. Attached as Exhibit 20 is a true and correct copy of email thread between E. Dittmann and S. Auten dated May 8, 2018. (Filed under seal).
22. Attached as Exhibit 21 is a true and correct copy of FDA Orange book information as to expiration of 180-day exclusivity pertaining to generic ALOXI®.
23. Attached as Exhibit 22 is a true and correct copy of April 27, 2018 email from E. Dittmann to S. Auten. (Filed under seal).
24. Attached as Exhibit 23 is a true and correct copy of April 4, 2018 letter from S. Auten to A. Miller. (Filed under seal).
25. Attached as Exhibit 24 is a true and correct copy of April 5, 2018 letter from S. Auten to E. Abraham. (Filed under seal).
26. Attached as Exhibit 25 is a true and correct copy of April 25, 2018 email from F. Rodriguez to S. Auten. (Filed under seal).
27. Attached as Exhibit 26 is a true and correct copy of April 19, 2018 email from E. Abraham to S. Auten. (Filed under seal).
28. Attached as Exhibit 27 is a true and correct copy of April 19, 2018 letter from S. Auten to Mses. Quinn and Pike. (Filed under seal).
29. Attached as Exhibit 28 is a true and correct copy of April 25, 2018 email from S. Auten to Mses. Quinn and Pike. (Filed under seal).

I hereby certify under penalty of perjury that the foregoing is true and correct.



Roshan P. Shrestha, Ph.D., Esq.

Dated: May 23, 2018